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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/532,585

04/25/2005

Kenshi Kamei

KAMEI2

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1444 7590 12/26/2006  
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|-----------|---------------|
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3 MONTHS

12/26/2006

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/532,585

Applicant(s)

KAMEI ET AL.

Examiner

Phyllis G. Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10 and 15-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10 and 15-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/11/06;11/6/06;12/8/06</u> . | 6) <input type="checkbox"/> Other: _____  |

Applicants' Amendment filed September 29, 2006 is acknowledged. Claims 1-9, 11-14 and 20 are canceled. Claims 10 and 15-19 remain under consideration.

Information Disclosure Statements filed August 11, 2006 and November 6, 2006, and a corrected form 1449 on December 8, 2006, are acknowledged and have been reviewed.

Claims 4-9 were objected to under 37 CFR 1.75(c), in the last Office Action as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Following cancellation of the claims, the objection is moot.

In the last Office Action claims 1-20 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention. All active claims are presently drawn to methods of treating constipation. Accordingly, the rejection of record under 35 U.S.C. 112, first paragraph, is withdrawn.

Claims 1-20 were rejected under 35 U.S.C. 102(b) in the last Office Action as being anticipated by Peeters, T.L., Current Opinion in Investigational Drugs (abstract). It was asserted Peeters teaches the administration of a composition comprising GM-611, an erythromycin derivative of the formula of instant claim 1. Instant R<sub>1</sub> is isopropyl and instant R<sub>2</sub> is methyl. According to Peeters, GM-611 is used to treat gastric motility disorders. The drug promotes peristalsis in the gastrointestinal tract.

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Applicants have supplied a complete copy of the reference and argue Peeters does not include treating constipation. Applicants urge Peeters does not include any reference as to whether the peristaltic effect of GM-611 would extend to peristalsis in the gastrointestinal tract as to treatment of constipation.

Applicants' argument is persuasive, and the rejection of record under 35 U.S.C. 102(b) is withdrawn.

Applicants' arguments with respect to a potential rejection under 35 U.S.C. 103, as being unpatentable over Peeters, T.L., Current Opinion in Investigational Drugs, have been considered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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Claims 10 and 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Ashley et al., U.S. Patent 6,562,795.

Ashley teaches the administration of the compound of instant Formula 1 to treat chronic constipation, also known as colonic inertia. See claims 4-6, columns 35 and 36. As taught by Ashley, GM-611, the compound of claim 4, wherein R<sup>1</sup> is hydroxyl, R<sup>3</sup> is isopropyl, R<sup>6</sup> is methoxy and R<sup>8</sup> is ethyl, is a prokinetic agent that is effective for the treatment of gastrointestinal motility disorders. Accordingly, by definition, a prokinetic agent accelerates motion. Thus, as required by instant claim 19, GM-611 accelerates normal defecation. As required by claims 15, 16 and 18, constipation, regardless of its etiology, i.e., that induced by an analgesic; by a functional bowel disorder, such as irritable bowel syndrome; or through age-related decreases in intrinsic colonic reflexes, low-fiber diets or lack of exercise, would be encompassed in Ashley's teaching of treatment of chronic constipation through the administration of GM-611.

No claim is allowed.

Clark et al., Clinical and Experimental Pharmacology and Physiology, is cited to show further the state of the art.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, may be reached on 591-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 17, 2006

  
Phyllis G. Spivack

**PHYLLIS SPIVACK  
PRIMARY EXAMINER**